REMARKS

Formalities

Claims 22-27 are pending and were rejected by the Examiner. Applicant requests reconsideration of the application in light of the arguments set forth below.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 22-27 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses this rejection.

In the enablement rejection, the Examiner has asserted that the specification does not provide an enabling disclosure for how to use the transgenic mouse as claimed. In particular, the Examiner asserts that the specification does not provide a specific teaching on how to use the claimed transgenic mice with a phenotype of anti-depressive behavior for the asserted use of screening for drugs or as a model for disease. Applicant respectfully disagrees, and believes that the rejection is overcome in light of the arguments below.

Applicant disclosed in the specification production of a transgenic mouse whose genome comprises a disruption in the NTTP1 gene, wherein the transgenic mouse exhibits as a result of the disruption a phenotype of anti-depressive behavior or an increase in time spent immobile while tail suspended. Applicant proposed and described in the specification several potential uses for the claimed transgenic mouse, such as, for example, screening for or characterizing drugs or putative therapeutic agents useful in modulating the anti-depressive phenotype, or for a model of anti-depressive behavior (see, for example, page 2, lines 19-26 and page 16, line 9 through page 17, line 26, of the specification).

Applicant submits that a person of skill in the relevant art would know how to use the claimed transgenic mouse. The utility of transgenic knockout animals, and in particular knockout mice, is well recognized in the art, and it is generally accepted that such transgenic knockout mice represent a valuable method for determining the function of genes. In the present case, Applicant's disclosure related to the phenotype of the transgenic mice has established that this gene plays a role in conditions or disorders related to depression. More particularly, the claimed transgenic mouse represents a model of antagonism of the NTTP1 gene, which results in

anti-depressive behavior, indicating that therapeutic agents or known drugs that mimic this effect on the NTTP1 gene (or gene product) would be potentially efficacious in the treatment or prevention of depression. The value of such an *in vivo* model would be immediately apparent to a person skilled in the art, in light of the homology between the mouse and human genomes, and the general acceptance that gene function in the mouse is related to and representative of that of humans. This is evidenced by the trend in the art to produce transgenic animals or mice with disruptions in all genes.

One aspect of the Examiner's rejection relates to an alleged lack of relation between the phenotype exhibited by the claimed mice and a specific disease. However, Applicant contends that the increased immobile time exhibited during the tail suspension test is well correlated to depression. This test is commonly used in the art to screen for phenotypes related to depression in transgenic knockout mice. Despite that Applicant believes that the phenotype is correlated to depression, Applicant is not aware of any standard that requires such a correlation in order to establish that a skilled artisan would know how to use the claimed mice. Applicant believes that the description of a phenotype is sufficient to enable the skilled artisan to use the mouse.

In another aspect of the rejection, the Examiner has asserted that behavioral phenotypes in mice as a result of a genetic mutation are unpredictable. However, Applicant demonstrated that a null mutation in a transgenic mouse whose genome comprises a disruption in the NTTP1 gene resulted in lack of production of the NTTP1 protein and a specific phenotype, anti-depressive behavior. The specification provides sufficient detail to enable the skilled artisan to create the mouse with the claimed phenotype. Such a mouse would be useful in the characterization and identification of therapeutic agents capable of modulating depression related behavior. Applicant notes that the claimed mouse would also have utility for determining the specificity of putative or known agents related to the treatment of depression. Furthermore, the transgenic mice would clearly be useful for characterizing the role of the NTTP1 gene in depression, and would provide an *in vivo* model useful for such a purpose. Applicant submits that, in addition to the potential uses asserted by Applicant, any number of other means of using the transgenic mouse would be clearly obvious to the skilled artisan, as supported by their perceived value in the art. A market exists for the characterization of every gene through the production and evaluation of transgenic knockout mice, which mice are produced and sold to customers in need.

Applicant submits that the arguments above overcome the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph. Applicant submits that the pending claims are clearly supported by an enabling disclosure in accordance with 35 U.S.C. § 112, first paragraph. Applicant requests withdrawal of the rejection.

It is believed that the claims are currently in condition for allowance, and notice to that effect is respectfully requested. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1271 under Order No. R-690.

Respectfully submitted,

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